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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,402	10/05/2001	Mark A. Gallop	033053-034	3864
21839	7590	02/09/2004	EXAMINER	
BURNS DOANE SWECKER & MATHIS L L P			MELLER, MICHAEL V	
POST OFFICE BOX 1404			ART UNIT	
ALEXANDRIA, VA 22313-1404			PAPER NUMBER	
			1654	

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/972,402		GALLOP ET AL.	
	Examiner		Art Unit	
	Michael V. Meller		1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2 and 43-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2 and 43-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

The invention is drawn to a compound having a formula (I). The compounds vary distinctly in their structures. Thus, an individual compound search is required of each individual compound (species) which cannot even be determined in this case.

Therefore, as part of the election/restriction since applicant elected Group II and the specific compound in Figure 10, compound (4), the examination of this application will be limited to this compound.

Applicant's election with traverse of Group II, claim 2 and the compound in figure 10, compound 4 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the search of the inventions will overlap since the inventions are so closely related to one another. This is not found persuasive because the inventions are not closely related to each other at all. Applicant is reminded of the extensive literature search for each compound and method which is not co-extensive. Each of the methods have different modes of operation and effects from one another and the compounds are structurally distinct from one another which is on the record. Each of the compounds is structurally distinct from one another and each require a different search. The independent claims claim extremely broad structures which are impossible to carry out a reasonable search on. Thus, the examination of the subject matter herein is limited to the compound in figure 10 compound 4 as elected by applicant.

Applicants did not acknowledge this requirement. It is still maintained for the above reasons.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 43-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has only described the particular compound in figure 10, compound 4. Applicant has not shown that they were in possession of any and all compounds encompassed by the claims. The specification only describes possession of this particular compound. Without any showing that any other compound encompassed by the claims applicant was in possession of at the time the invention was made, the invention is properly rejected under this section.

Applicants argue that they have provided examples illustrating how the synthesis of drug/linker/transporter conjugates could be conducted in order to prepare the presently claimed compounds.

The claims are very broad. Even as amended, applicant has amended the compound D-Y-T to for example, limit D to being a drug containing at least one moiety selected from the group consisting of hydroxyl, thiol, etc. How does this limit the claim to anything that could possibly be searched and understood at all ? The claims are simply way out of the realm of being able to be searched with the unbelievably broad language that applicant suggests. The examination of these claims is limited to the structure noted above in the restriction/election requirement as clearly outlined above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 43-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are written in such confusing language. For example, what is meant by "a drug having therapeutic or prophylactic activity when delivered to the systemic circulation of said animal". What animal ? What activity is being contemplated ? This is simply not clear. Further how can "T" be a moiety selected to permit the compound of formula I to be translocated across the intestinal wall of an animal if "T" is part of the compound of formula I. It simply is not clear what these symbols (D,Y and T) stand for in the claim.

These claims are still confusing. Applicant's amendments have not cleared up the confusing claims. Applicant's comments concerning "an animal" are noted but what does this have to do with the compound.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'M. Meller', with a long horizontal line extending to the right.

Michael V. Meller
Primary Examiner
Art Unit 1654

MVM